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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,159	11/05/2001	Timothy W. Lovenberg	ORT-1528	8725

7590 09/25/2003

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,159	LOVENBERG ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claims are directed toward a transgenic mouse having a disruption of an endogenous histamine H3 receptor that is insensitive to amnesic effects of scopolamine as compared to a wild-type mouse. The specification teaches H3-/- mice are resistant to the amnesic effect of scopolamine (pg 10, lines 3-25; pg 17, line 21, through pg 18, line 9). The specification does not teach how to use mice that are resistant to the amnesic effect of scopolamine. The art at the time of filing did not teach how to use such a mouse. Since the time of filing, Toyota (2002, Mol. Pharmacol. Vol. 62, pg 389-397, co-written by the inventors) taught H3-/- mice are resistant to the amnesic effect of scopolamine (pg 396, col. 1, 13-14). However, Toyota does not teach how to use such mice. Toyota concludes the mice should prove important for "elucidating the role of H3 receptors in a variety of peripheral and CNS functions as well as the pathophysiological states that are associated with altered histaminergic activity" (pg 396, col. 2, last sentence). Therefore, while the phenotype of the mouse is specific, the function of H3 receptors in the role of the amnesic effect of scopolamine is not. The insensitivity to scopolamine implies H3 receptors merely play a role in "passive avoidance." It remains unknown how H3 receptors function in the amnesic effect of scopolamine. Overall, the

specification does not provide a specific or substantial utility for a mouse that is resistant to the amnesic effect of scopolamine as claimed. Claims 5-6 are included because they are directed toward making the mouse. Claim 7 is included because the cell is isolated from the mouse and because no additional use for the cell alone has been provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-4 are directed toward a transgenic mouse having a disruption of an endogenous histamine H3 receptor that is insensitive to amnesic effects of scopolamine as compared to a wild-type mouse. The specification teaches H3-/- mice are resistant to the amnesic effect of scopolamine (pg 10, lines 3-25; pg 17, line 21, through pg 18, line 9). The specification does not teach how to use mice that are resistant to the amnesic effect of scopolamine. The art at the time of filing did not teach how to use such a mouse. Since the time of filing, Toyota (2002, Mol. Pharmacol. Vol. 62, pg 389-397, co-written by the inventors) taught H3-/- mice are resistant to the amnesic effect of scopolamine (pg 396, col. 1, 13-14). However, Toyota does not teach how to use such

mice. Toyota concludes the mice should prove important for "elucidating the role of H3 receptors in a variety of peripheral and CNS functions as well as the pathophysiological states that are associated with altered histaminergic activity" (pg 396, col. 2, last sentence). Therefore, while the phenotype of the mouse is specific, the function of H3 receptors in the role of the amnesic effect of scopolamine is not. The insensitivity to scopolamine implies H3 receptors merely play a role in "passive avoidance." It remains unknown how H3 receptors function in the amnesic effect of scopolamine. The specification merely states the model will allow the "definition of the function of histamine H3 receptor which is critical in deciding the types of modulators are most suitable in therapies" (para. bridging pg 7-8). Overall, the specification does not provide adequate guidance for one of skill in the art at the time of filing to determine how to use a mouse that is resistant to the amnesic effect of scopolamine as a model for any neural disorder or any disease associated with altered histaminergic activity. Even if one of skill used to mouse claimed to screen compounds that altered the "insensitivity to scopolamine" or to "evaluate the therapeutic effects of drugs that modulate the function or expression of histamine H3 receptor equivalents" (pg 2, line 13-15), the specification does not describe how to use mice that are insensitive to the amnesic effect of scopolamine to evaluate drugs that modulate H3 receptors, how to use compounds obtained from such an evaluation or diseases affected by compounds obtained from such an evaluation. Without teaching the function of H3 receptors or correlating a disruption of H3 receptor to a specific disease, the specification does not enable one of

skill to use the mice claimed. Therefore, it would require one of skill undue experimentation to determine how to use the mouse claimed.

The claims encompass any disruption of any histamine H3 receptor. First, the claims do not even require disrupting the H3 receptor gene, which is the only means of disrupting the H3 receptor disclosed in the specification. Second, the only mouse tested was a mouse homozygous for the disruption (Fig. 1 and 2), which is the only type of disruption that cause the phenotype claimed. Third, H3 receptors are a subtype of histamine receptor and encompass at least 2 types (West of record, 1990, Mol. Pharmacol., Vol. 38, pg 610-613). However, the specification does not teach which H3 receptor was disrupted or that a disruption in any H3 receptor causes the phenotype claimed. Therefore, the specification does not provide adequate guidance enabling any disruption in any H3 receptor causes the phenotype claimed.

Claims 5-6 are included because they are directed toward making the mouse. Claim 7 is included because the cell is isolated from the mouse and because no additional use for the cell alone has been provided.

Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "gene" in claims 2-4 lacks antecedent basis.

The phrase "a mouse blastocysts" in claim 5, item b) is grammatically incorrect.

The phrase "the blastocyst" in claim 5, item c) lacks antecedent basis.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

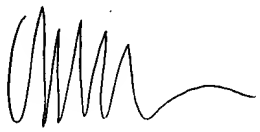
Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER